IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC.,	)	**REDACTED PUBLIC VERSION**
Plaintiffs,	)	
v.	)	C.A. No. 05-768-SLR
CONOR MEDSYSTEMS, INC.,	)	
Defendant.	)	

CONOR'S ANSWERING BRIEF IN OPPOSITION TO BSC'S *DAUBERT* MOTION TO STRIKE THE EXPERT REPORT AND TESTIMONY OF JACOB (KOBI) RICHTER

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INTRODUCTION

BSC has filed a so-called Daubert motion seeking to strike the expert report and testimony of Dr. Jacob (Kobi) Richter. In fact, the motion does not challenge the scientific basis of the evidence on which Dr. Richter will rely and so is not a Daubert motion at all. Instead, BSC claims that Dr. Richter's report is not really an expert report and that it is instead a disguised effort to offer facts that would otherwise not be admissible at trial. BSC further contends that, if its motion is granted, then Conor's other experts should be barred from relying on facts disclosed by Dr. Richter as part of the their opinions.

This motion is baseless. Dr. Richter has expert testimony to give, based in part upon his own personal knowledge and experience. Indeed, BSC has itself used Dr. Richter as an expert in the past in similar circumstances. Conor disclosed Dr. Richter as an expert witness during the expert discovery period and produced his expert report. BSC has taken his deposition, including questioning him about the facts that support his opinion. That is all that the rules require. In any event, Conor's other experts are fully entitled to rely on materials produced by Dr. Richter. They are stent designs – materials reasonably relied upon by persons of skill in the field of stent design.

FACTS

A. Dr. Richter Is an Expert in Stent Design and Manufacturing

Dr. Richter, as founder, Chairman and Chief Technical Officer of Medinol, a company that has worked on stent design and manufacture since 1992, is undoubtedly an expert in stent design. See Ex. A ¶¶ 1, 4, 6. Conor offers him as an expert on the issue of the state of stent art in the mid-1990s. During that time period, he was involved in the design of the NIR stent, and was aware of the problems stent makers were attempting to solve and the design

choices available to them in solving the problems. Id. ¶¶ 4, 8-17. Since 1994, Dr. Richter has filed for and received over 60 patents on stent or related technology. Id.

In Cordis Corp. v. Medtronic Vascular, Inc. et al., C.A. No. 97-550, ***BSC*** qualified Dr. Richter as an expert on the "design, structure, characteristics, functioning and performance of the NIR stent." Ex. B ¶ 7.[1] His report offered no ultimate opinions on any issues and it contained an extensive discussion of facts regarding the NIR stent. See id. ¶¶ 1-25. In his trial testimony, he discussed the problems facing stent designers in the mid-1990s, the design process of the NIR stent, and the features and workings of Medinol's stents. Ex. C at Tr. 755-67. It is this same expertise that Conor seeks to draw upon here.

Dr. Richter's expertise in stent design and the state of the art in the mid-1990s was made abundantly clear during his deposition in this case. See, e.g., Ex. D at 20-21 ("*Q.* And is it fair to say that over this time [since 1993] you have been continually working to try to improve stents and stent technology? *A.* Stents, stent technology and stenting application, yes."); id. at 26-31, 76-77 (discussing problems facing stent designers in early- and mid-1990s); id. at 32-34 (discussing design work on connectors done by Medinol in the early 1990s); id. at 57-58 (noting that he has done many simulations of stent designs to see how they behave, and personally seen how many stents behave); id. at 79-80 (discussing the properties of a stent that make it flexible); id. at 21, 86-87 (noting that he continues to work on stent design).

[1] Dr. Richter's report in the 97-550 case, like his report in this case, was not designated confidential and contains only Medinol information, not BSC information. Nonetheless, BSC has asserted without explanation that Dr. Richter's earlier report is confidential and so we are filing the report under seal, together with this brief and the other exhibits.

B. Dr. Richter's Report in This Case Sets Forth His Expert Opinion

Dr. Richter's report begins by stating his qualifications, including his education and his work with stents as Chairman and co-founder of Medinol. Ex. A ¶¶ 1-5. The report then discusses Medinol's design work as it relates to his opinions being offered in this case. Dr. Richter describes, with examples, work that appears in published patents and work that was not published, but that evidences the level of skill in the art. Id. ¶¶ 8-17. After this discussion, Dr. Richter opines that:

> By April 1996, and also by April 1997, because of our work at Medinol and the work of others, the fundamentals of stent design were well known. Stents with a combination of adequate support, both in strength to resist the tendency of the vessel to renarrow and in the stability of scaffolding, and adequate flexibility before and after expansion were known in the art. Specifically, stents that were flexible because the connectors provided such flexibility were known. In those stents, the connectors were curved in order to let them lengthen and shorten as the stent flexed. A line connecting the end-points of the connectors could be parallel to the stent's longitudinal axis or could be offset from the longitudinal axis.

Id. ¶ 18. Dr. Richter is not offering ultimate opinions on the obviousness or invalidity of the patent at issue; rather, he is testifying about the state of stent design during the period in which the patent applications at issue were filed.

Thereafter, BSC extensively explored Dr. Richter's opinions and the bases of those opinions at his deposition. It examined him in detail on the design choices available to stent designers in 1996. In particular, BSC thoroughly explored Dr. Richter about his personal knowledge about those choices, including extensive questioning about the work done by Medinol in the early to mid-1990s. Thus, BSC had the full opportunity to explore both Dr. Richter's opinion and the personal knowledge and experience on which it was based. See, e.g., Ex. D at 83 (explaining where stent designers in 1996 would prefer to have the connection point of connectors and why); id. at 94-98 (discussing different ways in which a connector might be

formed in order to achieve flexibility that were known in 1996); id. at 102-05 (discussing what an average designer in 1996 would take away from certain stent designs); id. at 13-14 (discussing Medinol's disclosure of its stent designs); id. at 23-26 (discussing Medinol's design work and exploring facts concerning the designs discussed in Dr. Richter's report); id. at 142-45 (discussing the Medinol design work cited in Dr. Richter's report).

ARGUMENT

BSC's suggestion that Dr. Richter's report is improper as an expert report because it contains factual information is misguided. Experts may properly rely on their "personal knowledge or experience" (to borrow a phrase from the Supreme Court) in providing their opinions. BSC's assertion that Dr. Richter's report "fails to set forth any opinions at all" is likewise incorrect. The report clearly states his views on the state of stent art in the mid-1990s, which is the subject of his expert testimony. BSC had no trouble understanding this, as shown by its deposition of Dr. Richter. BSC took a standard expert deposition exploring Dr. Richter's qualifications, opinions and the bases of those opinions.

I. DR. RICHTER'S OPINION ON THE STATE OF THE STENT ART IN THE MID-1990S, AND THE BASIS THEREFOR, IS ADMISSIBLE

BSC argues that Dr. Richter's report contains facts and that therefore it is not really an expert report. Indeed, it accuses Conor of offering Dr. Richter as an expert to circumvent the supposed fact that his testimony would not be admissible as trial as a fact witness. To the contrary, whether or not he is designated an expert, Dr. Richter can testify to the facts in his possession under this Court's rules.[2] Conor offers Dr. Richter as an expert on stent design because he *is* an expert on stent design and because Conor wishes to present his expert

[2] Dr. Richter can testify as a fact witness under this Court's Guidelines because his identity was disclosed during discovery and he has been deposed. For the same reason, he may produce documents in his possession as exhibits for use at trial and he has done so and been questioned about them.

testimony on that subject to the jury. For that reason, Conor timely disclosed his identity as an expert and provided BSC with an expert report setting forth Dr. Richter's opinions and the basis therefore. Likewise, for that reason, Conor produced Dr. Richter for deposition, allowing his opinions and the facts on which they were based to be fully explored by BSC.

Dr. Richter's expert testimony is admissible in all respects. A review of the Richter Report clearly demonstrates it satisfies all of the requirements of Fed. R. Civ. P. 26(a)(2)(B), including "a complete statement of all opinions to be expressed and reasons therefor." Specifically, the expert report contains a complete statement of Dr. Richter's opinion concerning the state of the stent art in the mid-1990s.

Expert testimony regarding the knowledge of people working in the field and the state of the art is an appropriate topic for expert opinions. Rule 702 allows experts to testify regarding "scientific, technical, or other specialized knowledge [that] will assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. Based on this rule, the Federal Circuit has repeatedly recognized the validity of expert evidence as to the knowledge of people working in the field at the time an invention at issue. Indeed, such evidence is relevant to understanding a patent, and in particular to determining whether a patent is obvious. E.g., Alza Corp. v. Mylan Labs., Inc., 464 F.3d 1286, 1294 (Fed. Cir. 2006) ("[W]here the testimony of an expert witness is relevant to determining the knowledge that a person of ordinary skill in the art would have possessed at a given time, this is one kind of evidence that is pertinent to our evaluation of a *prima facie* case of obviousness."); Fromson v. Anitec Printing Plates, Inc., 132 F.3d 1437, 1442 (Fed. Cir. 1997) ("The court may gain understanding of the state of the art at the time the invention was made, from the prior art or

from experts in the technologic field."), abrogated on other grounds by Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448 (Fed. Cir. 1998).

In forming his opinions, Dr. Richter is fully entitled to rely on facts within his personal knowledge and experience. As Federal Rule of Evidence 702 explicitly states, "[s]uch an expert may be qualified by [his] knowledge, skill, experience, training, or education." Id. Thus, as the Supreme Court has recognized, it is entirely proper for an expert to testify based on his "personal knowledge or experience." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 150 (1999); see also Cantor v. Perelman, 2006 WL 3462596, at *7 (D. Del. Nov. 20, 2006) (finding "no . . . bright line rule" that expert testimony should be "excluded when it is based entirely on experience and judgment, and not an identifiable methodology"); Stolt Achievement, Ltd. v. Dredge B.E. Lindholm, 447 F.3d 360, 366 (5th Cir. 2006) ("Kumho Tire recognized that experts may testify on the basis of their own 'personal knowledge or experience' and refused to hold that the Daubert factors must be addressed in every case, given the wide variety of experts and issues that may come before the district courts."); Fed. R. Evid. 702 advisory committee's note (explaining that "the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience"). Indeed, when BSC offered Dr. Richter as an expert in a different case, he relied on his personal experience and understanding. See Ex. B ¶¶ 1-25.

Nor is there any rule that, when an expert offers opinions based on "personal knowledge or experience," that personal knowledge and experience must be captured in a previously-established discovery record. Far from any such requirement, Rule 703 explicitly permits an expert to testify even based on "facts or data that are otherwise inadmissible." Fed. R. Evid. 703. Moreover, such a rule would make no sense. As BSC would have it, Dr. Richter would first have to be deposed as a fact witness about his personal knowledge and experience,

including any documents or exhibits he might have. Then he would submit an expert report relying on that personal knowledge and experience. And then he would be deposed again, this time about the opinions he formed based on his personal knowledge and experience. There is no support for such a senseless exercise. Instead, what happened here was just what the rules contemplate. Dr. Richter submitted his expert report, revealing both his opinions and the basis therefor. Then he was deposed by BSC, which explored at length in a single deposition both his opinions and the facts within his personal knowledge and experience upon which they were based.

Dr. Richter's report and testimony easily satisfy the requirements of the rules. Dr. Richter explains in his report the factual basis for his opinion by describing work done at his company, Medinol, during the early 1990's. Based on that factual recitation, which is described in detail and includes many examples of his personal experiences with stent design, he offers his expert opinion that "[b]y April 1996, and also by April 1997, because of our work at Medinol and the work of others, the fundamentals of stent design were well known." Ex. A ¶ 18. Dr. Richter then describes a variety of fundamentals of stent design, including – as directly relevant to this case – his opinion that curved connectors were known and that such curved connectors could be oriented so as to be either horizontal or offset. "Specifically, stents that were flexible because the connectors provided such flexibility were known. In those stents, the connectors were curved in order to let them lengthen and shorten as the stent flexed. A line connecting the end-points of the connectors could be parallel to the stent's longitudinal axis or could be offset from the longitudinal axis." Ex. A ¶ 18.

Dr. Richter's opinion that it was well known in 1996 that curved connectors could be either horizontal or offset goes directly to the obviousness issues in this case. As set forth in

detail in Conor's motion for summary judgment based on obviousness (D.I. 142), BSC contends that claim 35 of the Jang '021 patent is not obvious because it covers curvy, offset connectors. Conor contends, as Dr. Richter opines, that such connectors were already known in 1996. Moreover, Conor contends that claim 35 actually also covers curvy, horizontal connectors. Dr. Richter opines that such connectors also were already known in 1996. This is classic opinion testimony directed specifically to the issues in dispute.

Conor offers Dr. Richter to address these issues, not to offer ultimate opinions on obviousness or infringement. Such use of expert testimony is altogether proper. Again, when BSC offered Dr. Richter as an expert in a different case, he offered similar opinions and did not opine as to the ultimate issues in that case. See Ex. B ¶¶ 1-25. Here, Dr. Richter's opinion on the state of the art is appropriate expert testimony as it will assist the jury in making its determination on whether the differences between the prior art and the claims "would have been obvious . . . to a person having ordinary skill in the art." 35 U.S.C. § 103(a). As the Alza and Fromson opinions make clear, there is simply nothing improper about expert testimony on the state of the art.

The Richter Report establishes that Dr. Richter is qualified as an expert and is giving opinions on an appropriate topic that will assist the jury. Moreover, having similarly offered Dr. Richter's expert testimony in the past, BSC is in no position to object now. BSC's motion to strike should be denied.

II. CONOR'S OTHER EXPERTS MAY RELY ON DR. RICHTER'S REPORT

BSC argues that the portions of the reports of Drs. Buller and Solar that rely on the Richter report should be stricken and that Drs. Buller and Solar should be precluded from testifying at trial regarding anything in the Richter report. Tellingly, BSC points cites no authority supporting its argument. In fact, Federal Rule of Evidence 703 explicitly provides that

experts may rely on anything "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject" and that "the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted." See also Bauman v. Centex Corp., 611 F.2d 1115, 1120 (5th Cir. 1980) ("In general whether facts relied on by an expert are in evidence, or even could be in evidence, is not relevant. The pertinent inquiry under Rule 703 is whether the facts are of a type reasonably relied on by experts in the particular field. The object of this inquiry is of course to determine the reliability of the expert's testimony.").

Prior stent work, like that done by Medinol in the early to mid-1990s, is unquestionably the sort of evidence upon which experts on stent design rely. Conor disclosed Dr. Richter's report to BSC and BSC had the opportunity to, and did, address the report in its rebuttal reports. As discussed above, Dr. Richter's report should not be stricken. Even if it were, however, Conor's other experts should be entitled to rely on the facts disclosed in the report.

CONCLUSION

For the reasons set forth above, Conor respectfully requests that this Court deny BSC's motion to strike.

ASHBY & GEDDES

/s/ Lauren E. Maguire

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Dated: May 15, 2007
180581.v1

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., Plaintiffs, v. CONOR MEDSYSTEMS, INC., Defendant.	Civil Action No. 05-768-SLR

EXPERT REPORT OF JACOB (KOBI) RICHTER, Ph.d.

I am submitting this expert report in the above case.

1. I am the Chairman of the Board, Chief Technical Officer ("CTO") and substantial shareholder of Medinol, Ltd. ("Medinol"), the Israeli company which designed, developed and manufactures the NIR stent, a component of NIR premounted stent systems sold in the world by Boston Scientific Corporation ("BSC"). Within Medinol, as CTO, I am responsible for all technology-related work. including product research and development, the manufacturing facilities and quality assurance for all Medinol stent products, including the NIR stent.

2. In 1973, I received a B.Sc. in biology from Beer Sheva University. In 1976, I received a Ph.D. in medical science (physiology and pharmacology) from the Medical School of Tel Aviv University. During that time, I taught excitable tissue physiology (heart, nerve, brain and muscle) to medical students.

3. I served as a pilot in the Israeli Air Force between 1964 and 1986 with a leave of absence between 1979 and 1982. I undertook a one year post doctorate study from 1979

onwards at the Center of Cognitive Sciences at the Massachusetts Institute of Technology ("MIT") in Cambridge, Massachusetts. I then became a visiting research scientist at the MIT Artificial Intelligence laboratory for more than two years. During the three years I spent at MIT, I worked on research of visual information processing in biological systems and computer vision. Between 1982 and 1986, I was responsible for research and development ("R&D") as head of the operational requirements department of the Israeli Air Force. The R&D work was undertaken internally and externally and included materials, machine engineering, aeronautics and avionics. In 1986, I left the Israeli Air Force to take a management position in Orbot, a company which I had co-founded in 1980. Orbot specializes in automated optical inspection systems for the electronics industry (e.g., computer chip wafers, printed circuit boards, and components of LCDs). At Orbot, I was head of R&D, a new product development. and marketing until October 1992.

4. I co-founded Medinol, which was incorporated under Israeli law on December 23, 1992. Medinol was founded for the purpose of pursuing design and development of technologies for medical applications, including the design and development of stent technology. Among other activities, Medinol designed and manufactured the NIR stent.

5. I have twice been offered as an expert on stent design by Boston Scientific, and my testimony was accepted by the Court in both instances.

6. My professional background is more fully set forth in my curriculum vitae, which is attached as Exhibit A.

7. I considered the materials listed in this report in reaching the conclusions stated in this report.

8. In 1994, Medinol was in the process of developing a new stent. The first version of the stent designed by myself and Gregory Pinchasik, became the subject of U.S. Patent No. 5,449,373, figures from which are shown below:

FIG.2A

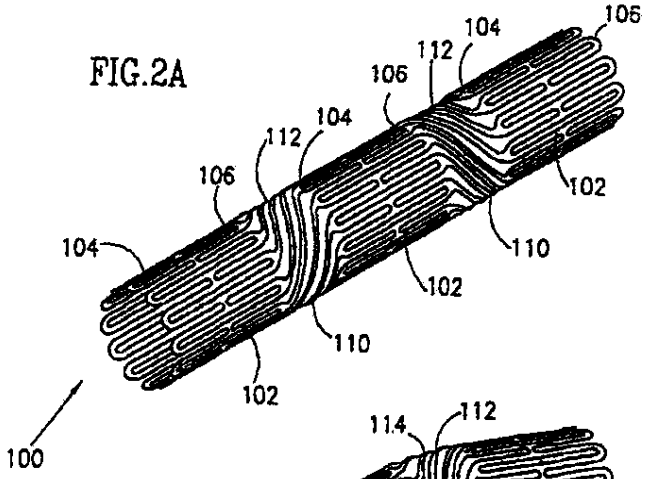


FIG.2B

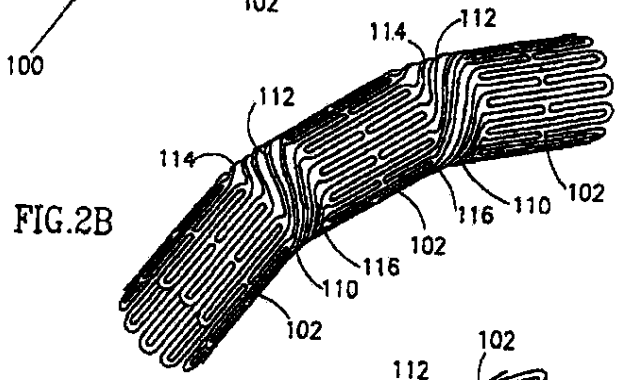


FIG.2C

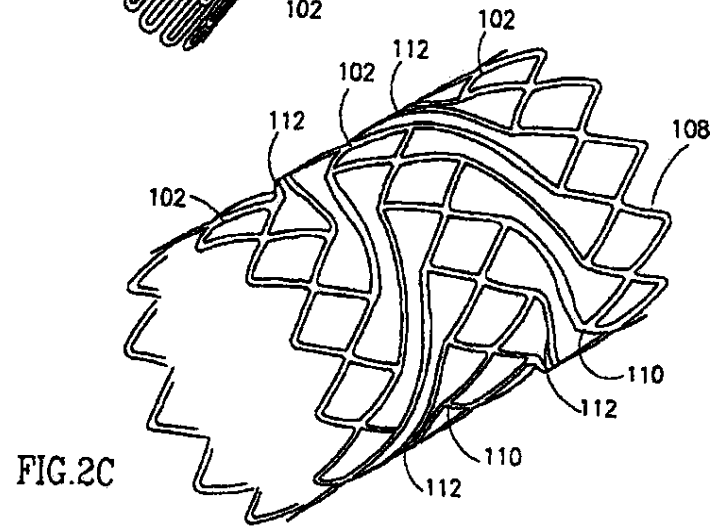


FIG.3A

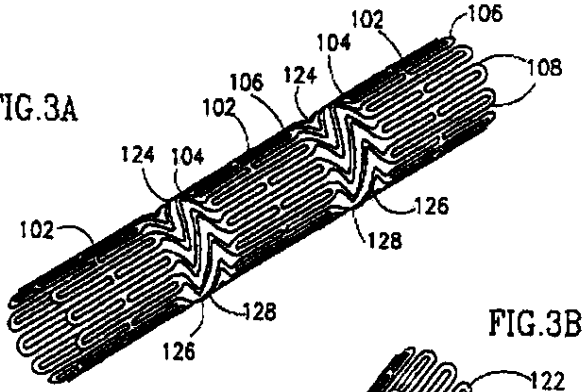


FIG.3B

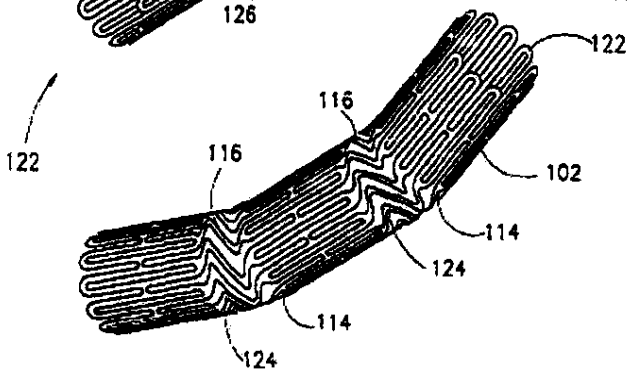
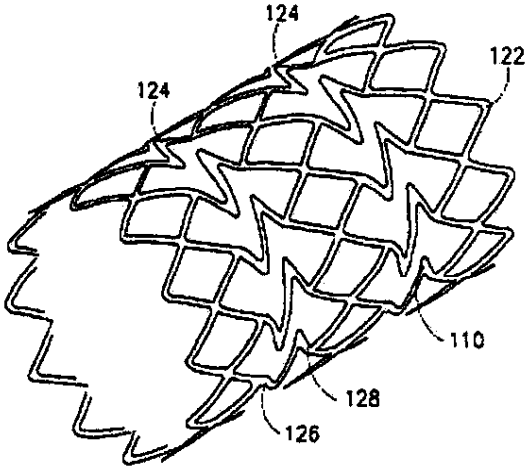


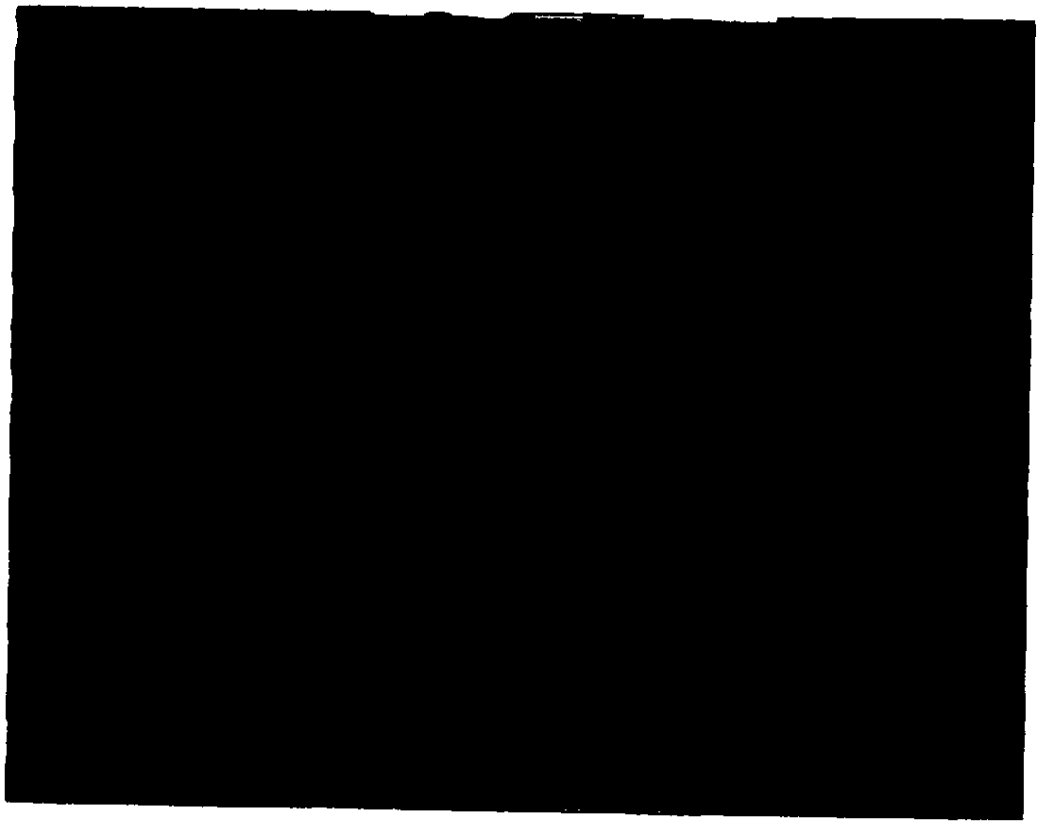
FIG.3C

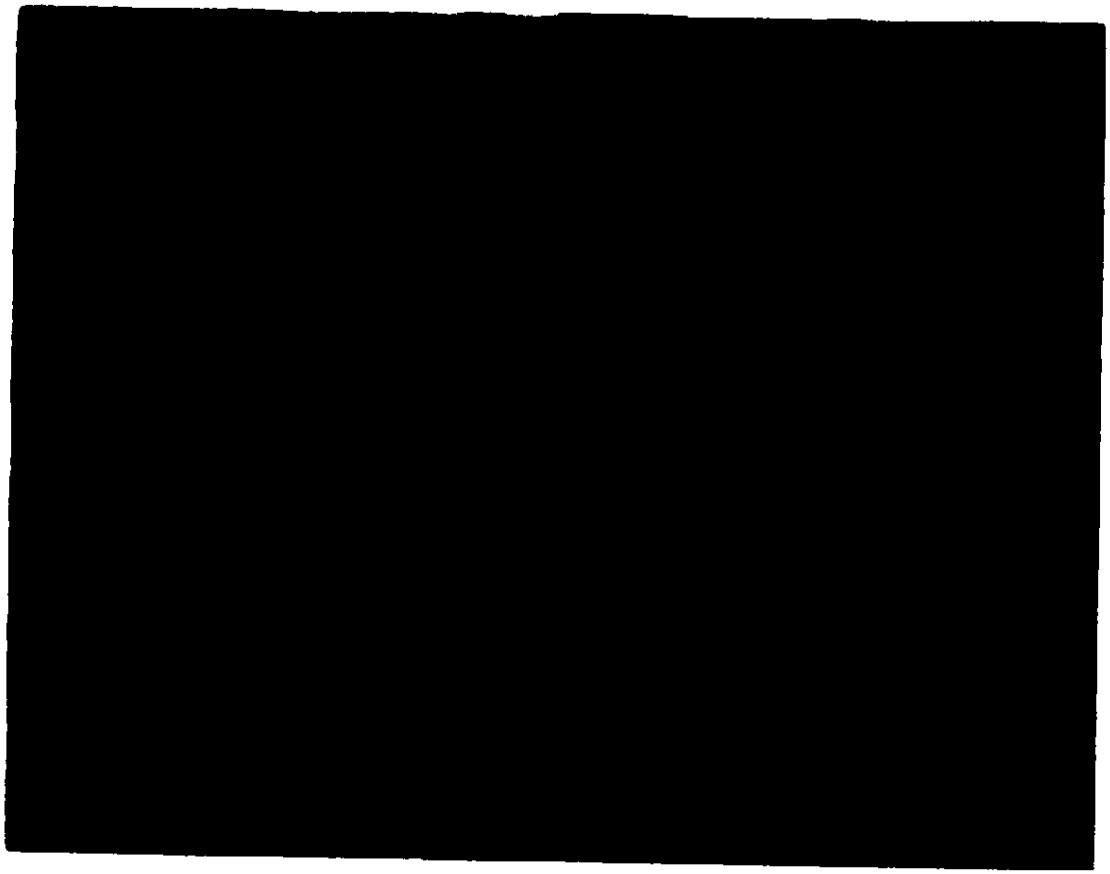


9. The two embodiments of the '373 design feature two different connectors. In the Fig. 2 design, the connectors are oriented so that a line drawn between the end points of the connectors is offset from the longitudinal axis of the stent when rendered in a two

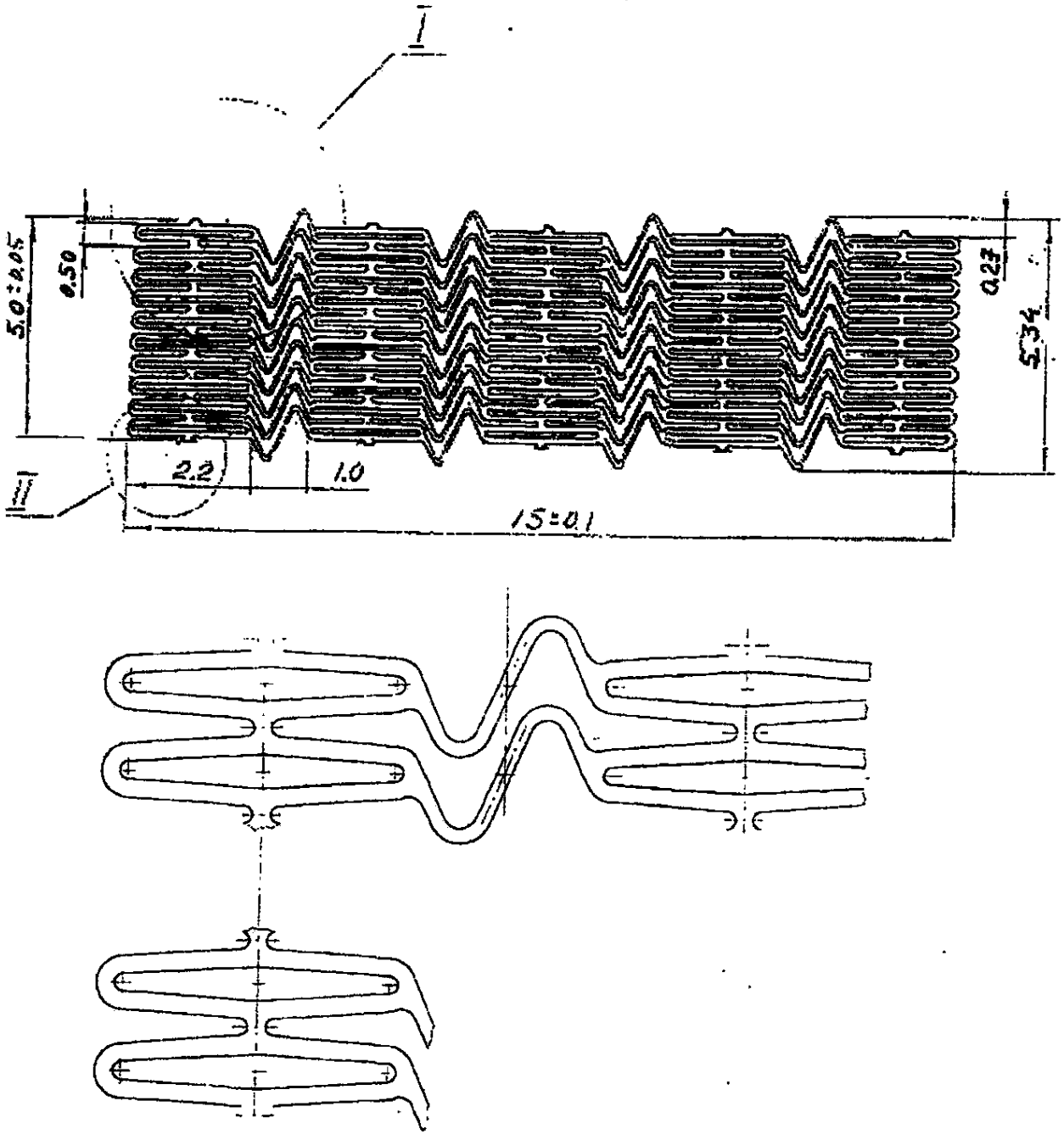
dimensional drawing. In the Fig. 3 design (the "lightning design"), the connectors are curved into what we called a "lightening bolt" and were oriented in a horizontal direction compared to the longitudinal axis of the stent when rendered in a two dimensional drawing.

10. After we designed the Figures 2 and 3 embodiments, Medinol created a stent in which the lightening bolt connector was used (as in Fig. 3), but was offset so that it connected the lower part of the loop on one side with the upper part of the loop on the other side. In or before mid-1994, Medinol chemically etched this design on metal. I still have sections of the etched panel in my possession. Photographs of the etched panel in different magnifications, are annexed hereto as Exhibits B, C and D, and are shown below:

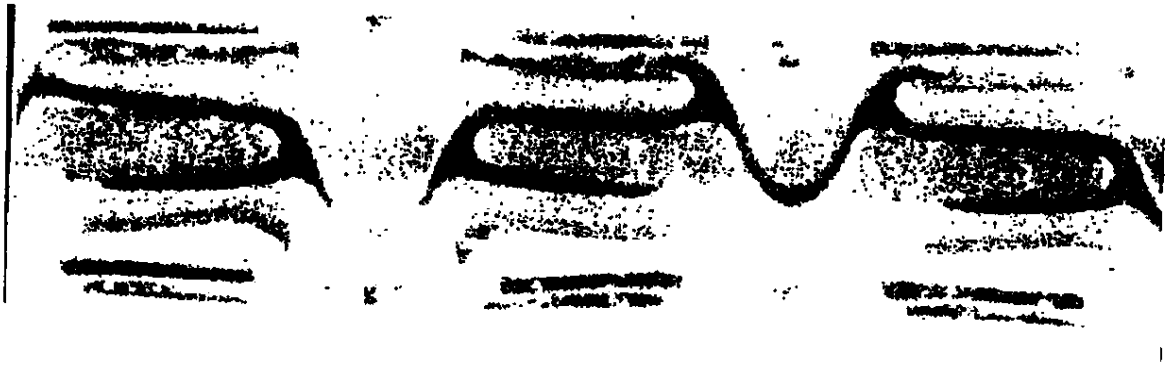




11. Manufacturing drawings of the same stent, from April 1994 or earlier (which were sent for manufacturing and weld inspection by April 1994), annexed hereto as Exhibits E and F, are below:



12. Medinol continued refining its stent design. In mid-1994 Henry Israel and Pinchasik designed what became known as the NIR stent, which is pictured below:



The basic design concept of the NIR stent is described in the patent that issued as U.S. Patent No. 5,733,303.

13. The NIR design performed far better than the predecessor lightning design, and, accordingly, Medinol focused its immediate attention on developing the NIR design.

14. Medinol continued work to improve stent design. In 1996, I designed a stent, based on the NIR model, in which I utilized a version of the curved connector that we had used on the lightning embodiments in 1994, with some of the connectors arranged so that a line drawn between the end points of those connectors is offset from the longitudinal axis of the stent when shown in a two-dimensional drawing. Those connectors are shown on the left in Fig. 11 of U.S. Patent No. 5,807,404:

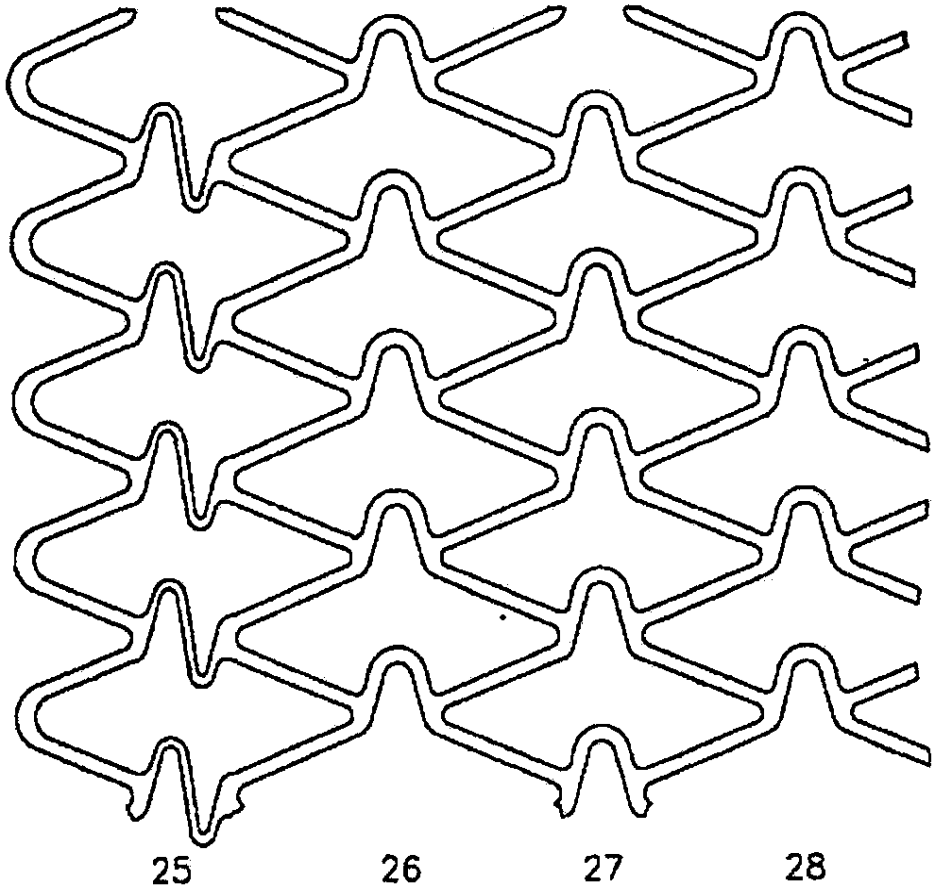
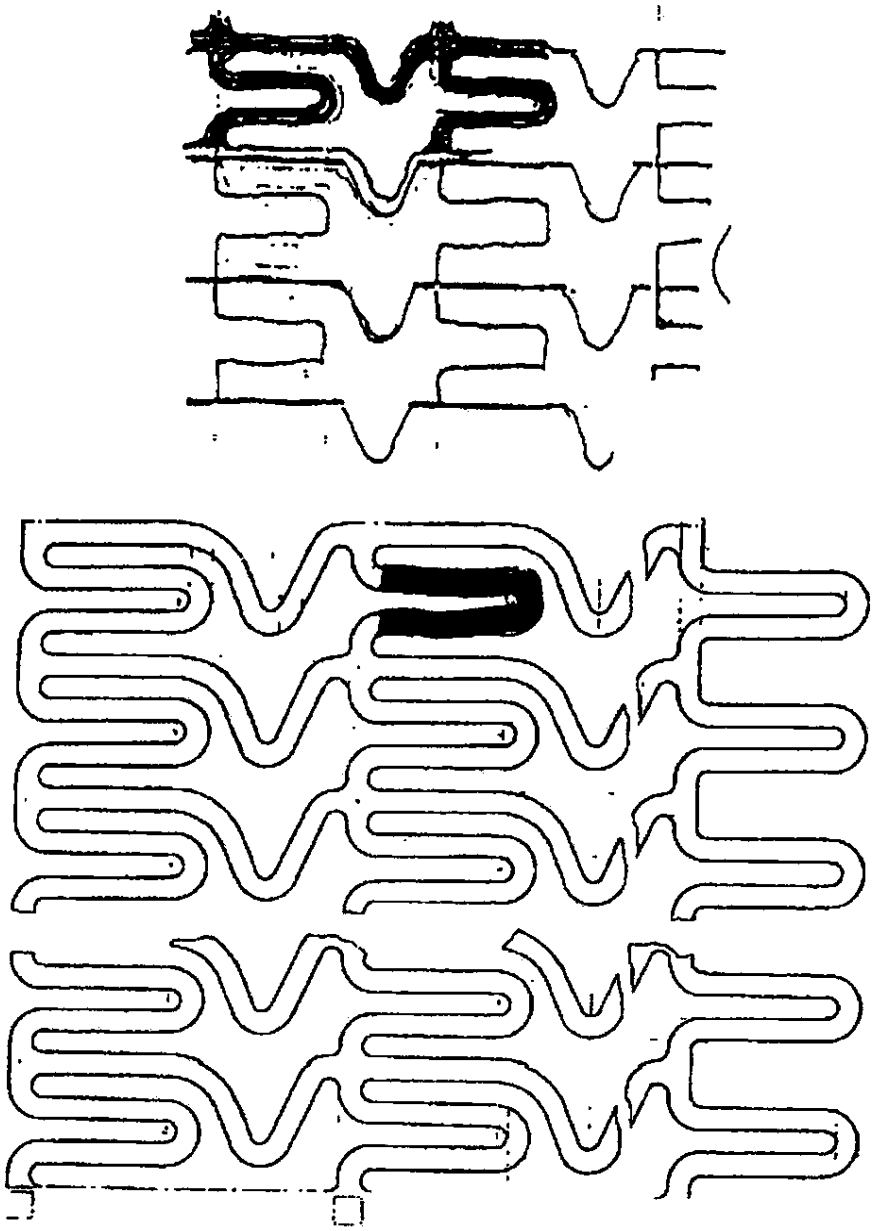


FIG. 11

15. Medinol's design work included both 180-degree out of phase designs and in-phase designs.

16. An example of a Medinol 180-degree out of phase design is the NIR stent, shown above.

17. Examples of Medinol in-phase designs are shown in the drawings annexed hereto as Exhibits G and H, drawn in late 1993 or early 1994, parts of which are reproduced below:



18. By April 1996, and also by April 1997, because of our work at Medinol and the work of others, the fundamentals of stent design were well known. Stents with a combination of adequate support, both in strength to resist the tendency of the vessel to renarrow and in the stability of scaffolding, and adequate flexibility before and after expansion were known in the art. Specifically, stents that were flexible because the connectors provided such flexibility were known. In those stents, the connectors were curved in order to let them lengthen

and shorten as the stent flexed. A line connecting the end-points of the connectors could be parallel to the stent's longitudinal axis or could be offset from the longitudinal axis.

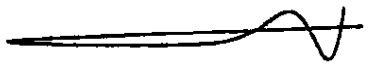
19. I have not yet decided on the exhibits to be used if I am called at trial, but these may include the various items referred to above, as well as diagrams, models, or photographs of the structures, functions and procedures described above. I may also use demonstrative exhibits and summaries that have not yet been prepared.

20. A list of my publications is included in my curriculum vitae, which is attached as Exhibit A.

21. I am being compensated for my services at the rate of $500 per hour.

22. Within the past four years, I have testified as an expert at trial or by deposition in the following cases: *Medtronic Vascular, Inc. v. Boston Scientific Corp.*, C.A. 98-478-SLR (D.Del.); and *Cordis Corporation v. Boston Scientific Corp.*, C.A. No. 97-550-SLR (D. Del.).

23. I may supplement this report if I become aware of any additional pertinent information or in response to the testimony of others. Moreover, I may comment on, or testify in response to, the testimony of other witnesses, including witnesses who testify on behalf of plaintiff.



Dr. Kobi Richter

Dated: March 18, 2007

Exhibit A to Richter Expert Report

CURRICULUM VITAE

DR. JACOB (KOBI) RICHTER

BUSINESS ADDRESS

Medinol, Ltd.
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EDUCATION

- B.Sc. – Biology, Beer Sheva University 1973
- Ph.D. – Medical Sciences, Tel Aviv University 1976

POST-GRADUATE EXPERIENCE

- 1979 – Post Doctoral studies, Massachusetts Institute of Technology (MIT), Cognitive Sciences.
- 1980 – 1982 – Research Scientist, MIT Artificial Intelligence Lab. and Brain Research Center.

CURRENT EMPLOYMENT

- Founder, Chairman of the Board of Directors, and Chief Technology Officer for Medinol.

PRIOR EMPLOYMENT

- Israeli Air Force 1964 – 1986
- Orbot, Founder & Head of Marketing and Product Development 1986 – 1992
- Marathon, Founder & General Manager 1993 – 1994

ISSUED PATENTS

Dr. Richter is a named inventor on the following United States Patents:

U.S. PATENT NO.	TITLE
6,736,838	Method and apparatus for covering a stent
6,723,119	Longitudinally flexible stent
6,709,453	Longitudinally flexible stent
6,692,522	Stent having lumen comprising welded engagement points and method of

	fabricating same
6,676,697	Stent with variable features to optimize support and method of making such stent
6,666,881	Method of heating a nitinol stent
6,660,019	Stent fabrication method
6,645,221	Active arterial embolization filter
6,589,276	Articulated stent
6,540,779	Bifurcated stent with improved side branch aperture and method of making same
6,508,834	Articulated stent
6,503,270	Serpentine coiled ladder stent
6,475,234	Balloon expandable covered stents
6,468,283	Method of regulating pressure with an intraocular implant
6,440,165	Bifurcated stent with improved side branch aperture and method of making same
6,436,134	Bifurcated stent with improved side branch aperture and method of making same
6,406,489	Bifurcated stent and method of making same
6,355,059	Serpentine coiled ladder stent
6,334,859	Subcutaneous apparatus and subcutaneous method for treating bodily tissues with electricity or medicaments
6,315,794	Multilayered metal stent
6,299,755	Stent fabrication method and apparatus
6,251,133	Bifurcated stent with improved side branch aperture and method of making same
6,238,401	Apparatus and method for selectively positioning a device and manipulating it
6,197,048	Stent
6,156,052	Stent fabrication method
6,152,878	Intravascular ultrasound enhanced image and signal processing
6,117,156	Bifurcated stent and method of making same
6,114,049	Stent fabrication method
6,095,976	Method for enhancing an image derived from reflected ultrasound signals produced by an ultrasound transmitter and detector inserted in a bodily lumen
6,090,133	Bifurcated stent and method of making same
6,059,811	Articulated stent
5,997,703	Stent fabrication method
5,980,552	Articulated stent
5,968,058	Device for and method of implanting an intraocular implant
5,964,770	High strength medical devices of shape memory alloy
5,922,005	Stent fabrication method
5,906,759	Stent forming apparatus with stent deforming blades
5,868,697	Intraocular implant
5,836,964	Stent fabrication method
5,827,320	Bifurcated stent and method of making same
5,807,404	Stent with variable features to optimize support and method of making such

	stent
5,782,905	Endovascular device for protection of aneurysm
5,755,735	Bifurcated stent and method of making same
5,755,734	Bifurcated stent and method of making same
5,702,414	Method of implanting an intraocular implant
5,620,457	Catheter balloon
5,449,373	Articulated stent

PUBLICATIONS
(as presently advised; limited to the preceding ten years)

- Yaron Almagor, Kobi Richter, Carlo Dimario, Akira Itoh, Lucia Difrancesco, Massino Ferraro, Luigi Maiello, Simonetta Blengino, Martin B. Leon, and Antonio Colombo, *Treatment of Long Lesions in Small Tortuous Coronary Vessels with a New Intravascular Rigid-Flex (NIR) Stent*, JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY, 27 (2 Supp. A) 110A (1996).

- Kobi Richter, Yaron Almagor, Martin Leon, *NIR Stent, Transforming Geometry, in* HANDBOOK OF CORONARY STENTS, chapter 15 (Patrick W. Surreys ed., 1997).

- Kobi Richter, Yaron Almagor, Martin Leon, *NIR Stent, Transforming Geometry, in* HANDBOOK OF CORONARY STENTS, chapter 14 (Patrick W. Surreys, Michael J.B. Kutryk eds., 2d ed. 1998).

- Kobi Richter, Yaron Almagor, Martin Leon, *The NIR and NIROYAL Coronary Stents, in* HANDBOOK OF CORONARY STENTS, chapter 34 (Patrick W. Surreys, Michael J.B. Kutryk eds., 3d ed. 2000).

- Kobi Richter, Yaron Almagor, Martin Leon, *The NIR and NIRFLEX Coronary Stents, in* HANDBOOK OF CORONARY STENTS, chapter 26 (Patrick W. Surreys, Benno Rensing eds., 4th ed. 2002).

Exhibit B to Richter Expert Report

Exhibit C to Richter Expert Report

Exhibit D to Richter Expert Report

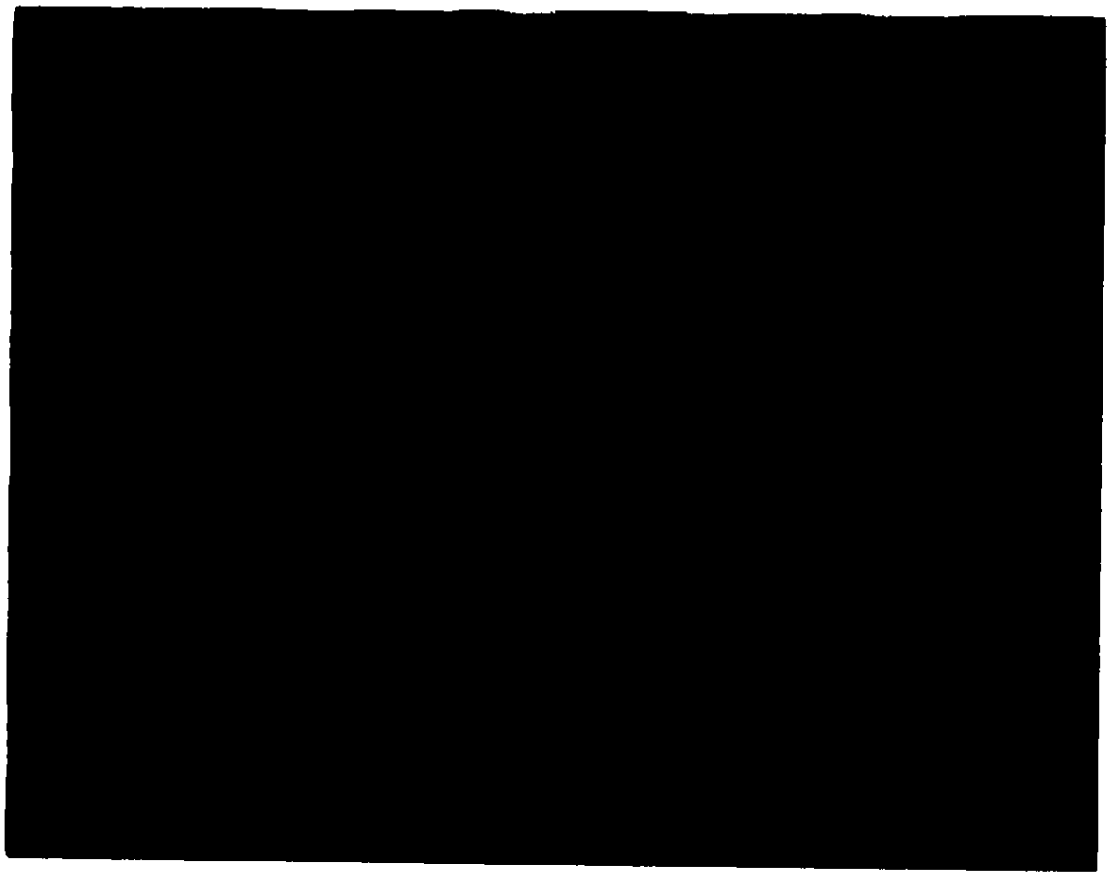
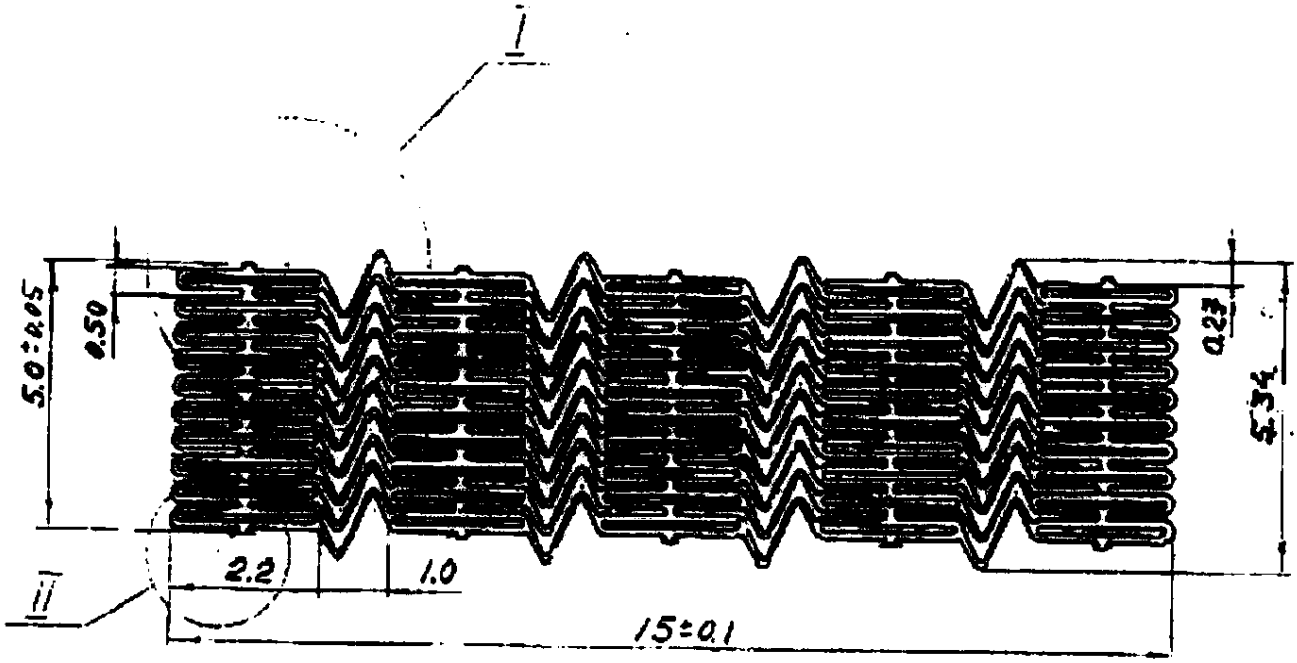


Exhibit E to Richter Expert Report


I
II
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0.50
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5.34
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Exhibit F to Richter Expert Report

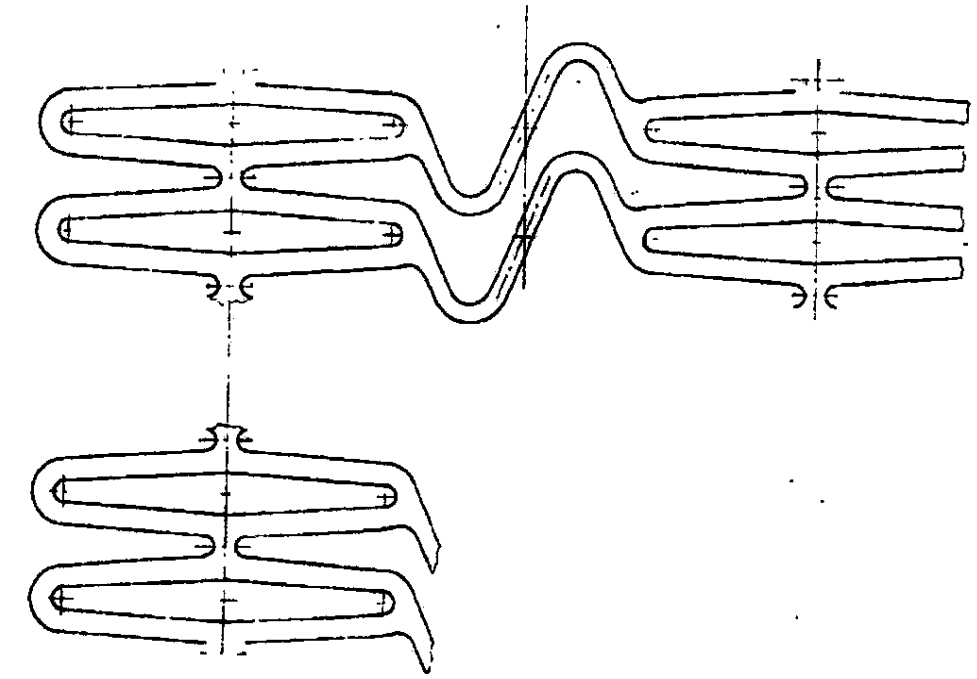


Exhibit G to Richter Expert Report

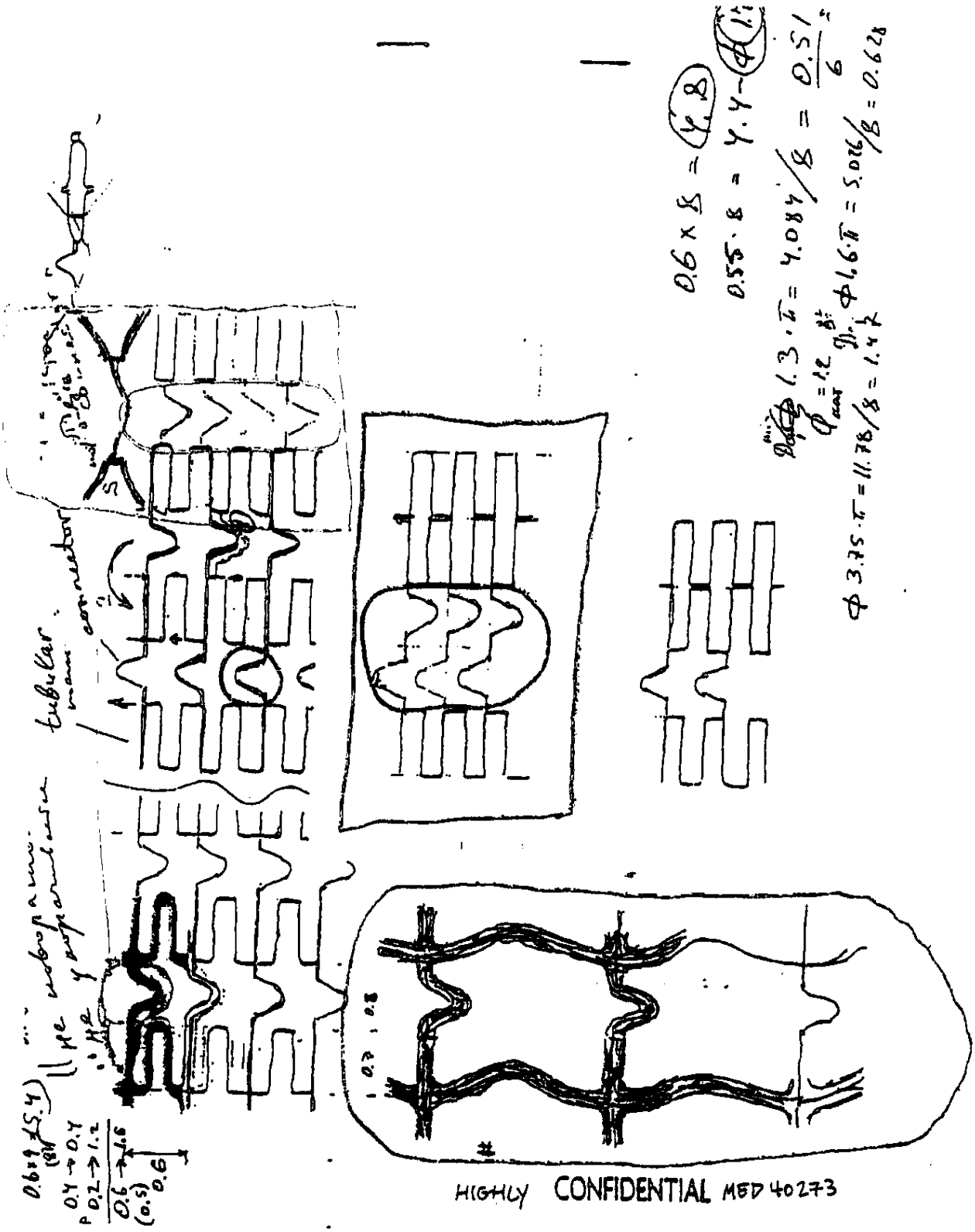
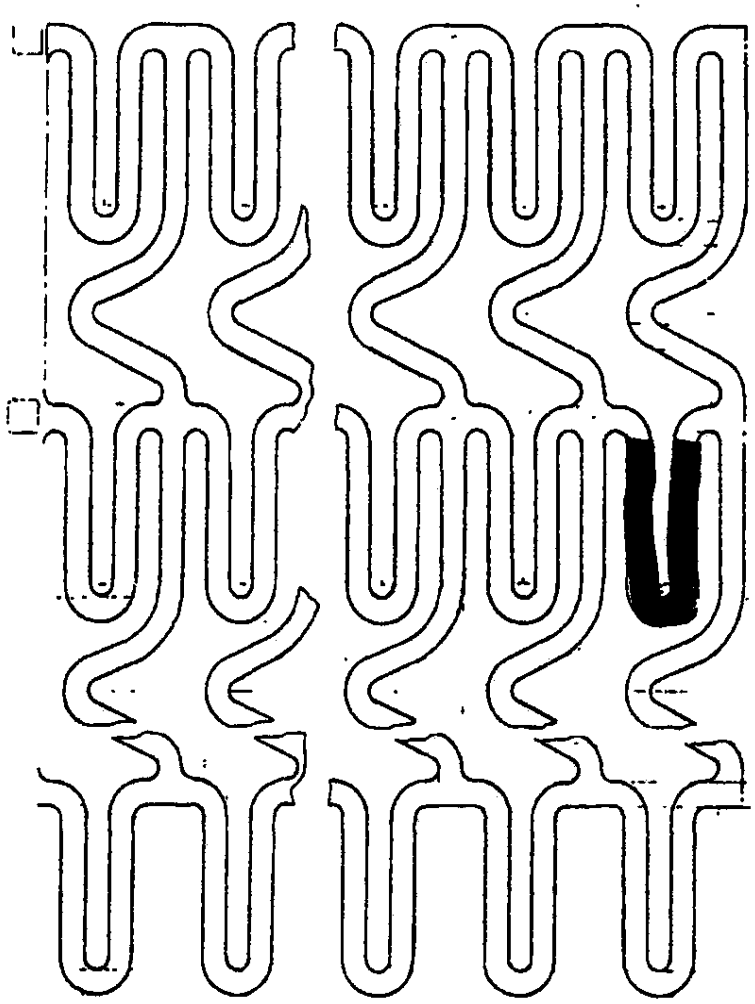


Exhibit H to Richter Expert Report



MGD 402 84
HIGHLY CONFIDENTIAL

EXHIBIT B

REDACTED

EXHIBIT C

- VOLUME C -

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

- - -

CORDIS CORPORATION, Plaintiff	:	CIVIL ACTION
vs.	:	
MEDTRONIC AVE, INC., BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., Defendants	:	NO. 97-550 (SLR)
BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., Plaintiffs	:	CIVIL ACTION
vs.	:	
ETHICON, INC., CORDIS CORP. and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO., Defendants	:	NO. 98-19 (SLR)
CORDIS CORPORATION, Plaintiff	:	CIVIL ACTION
vs.	:	
MEDTRONIC AVE, INC., BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., Defendants	:	NO. 98-197 (SLR)

- - -

Wilmington, Delaware
Monday, March 21, 2005
9:05 o'clock, a.m.

- - -

BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge, and a jury

- - -

Valerie J. Gunning and
Leonard A. Dibbs,
Official Court Reporters

BY MR. HANLEY:

Q. Dr. Richter, we're going to put up a pair of photographs. Can you identify what we're seeing here?

A. Yes. These are the two stents that I just named now. At the top here is the GR 1 stent, after deployment, so it's without the balloon.

And here on the left, on the bottom, is the Palmaz/Schatz, the two halves with the little bridge connecting them. This one is on a delivery balloon catheter, and bent.

Q. And what did you learn from physicians about the pluses and minuses, if you will, of these stents that influenced you in your pursuit of a stent design?

A. In relation to the GR 1 stent, they -- the strongest point was this stent was more flexible than the balloon it was on. So it allowed the physician to get anywhere they wanted or anywhere they could get with a balloon.

The major disadvantage was, as you can see, there's no connection between neighboring loops here, and if a lesion would be hard enough and wants to push into the lumen, it is very easy to push two loops apart and the lesion would still penetrate between them. It does not have to decrease the size of the loop, but just penetrate between two loops.

So the support of a structure like that is very, very poor. It is not rigid. It's very flimsy, even after you expend it.

I think Bob Croce here referred to that type of stent as slinkies. I think it's a nice analogy. And it's easy to move the loops apart.

So very flexible, gets anywhere, but supports almost nothing because things get between the loops.

The assessment of the Palmaz/Schatz was, first of all, it was very inflexible. It was more flexible than the Palmaz before it that did not have the articulation point. Physicians referred to it in my presence, trying to push a pencil down the vessel.

So this one certainly became two shorter pencils and hence easier to push or easier to reach some areas, but still, even that length of an inflexible section was a big hurdle to pushing the stent into the lumen.

There was another problem, which is you see that right here at the half, if we are pushing this stent let's say to the left here (indicating), the end of the loops here, of the second half, flare out, away from the balloon, and if it's against a vessel wall that is rough, they can latch on it and stop you from pushing forward.

So these were the two problems with inserting it.

Another major problem was that when this stent opens, that gap here between the two halves becomes -- can become very large, especially if this is a curved section. Now the gap would open to a few millimeters and this happens at the very center of the stent, where typically, not in all cases, the lesion is larger or harder. This is where you need the support.

So the problem with that one was its lack of flexibility and lack of support at the center. On the other hand, around the section itself, each section itself, its support was good, it was rigid, elements could not move away from each other. So if you touched a lesion, it would hold a lesion if it's next to that half, not next to the articulation.

Q. So from these discussions, what did you come away with by way of an agenda for designing a stent?

A. In a very generalized way, I would say that we wanted something that would support at least as good as the Palmaz/Schatz, right here, but track as good as the GR 1, which at that time, to physicians, seemed like two contrasting requirements that are hard to combine in one device.

Q. Now, did you believe that either of these devices,

the Palmaz/Schatz or the GR 1, were pioneering devices at that time?

A. I did then and I do today. I think that, first of all, almost by definition, the first device to appear for a given application, the first one is the pioneer. Then I think that the Gianturco and Dr. Palmaz, that you saw here, are definitely pioneers, who enabled this whole field.

I see, I think, that Palmaz's pioneering contribution is a great physician and even ten times greater entrepreneurs. Pushing something into use against resistance of the field, it has nothing to do with Palmaz as an inventor or a specific Palmaz invention.

As a matter of fact, the smaller the invention, the more impressive is the way he was able to push it forward. I'm not trying to now judge the invention. What I'm saying is that is what is impressive about him, is the rigor with which he pushed it forward and succeeded against formidable opposition.

Q. All right.

MR. HANLEY: Your Honor, I'm about to go on to a new subject. If this is a convenient time, otherwise we'll keep going.

THE COURT: I think we can take a break now.

15 minutes.

(At this point the jury was excused for a short recess.)

(Short recess taken.)

- - -

(Court resumed after the recess.)

THE COURT: All right. Let's bring our jury in.

(At this point the jury entered the courtroom and took their seats in the box.)

THE COURT: Mr. Hanley?

MR. HANLEY: Thank you, your Honor.

BY MR. HANLEY:

Q. Dr. Richter, let's go on and talk about the NIR stent. When was the NIR stent designed?

A. The NIR stent was designed around mid-'94, started the design of the NIR stent.

Q. And we have a couple of animations that you've helped us with and I'd like you to use them to explain the features of the NIR structure. So why don't we start with the first one.

And you can stop it. You can signal guy to stop it when you want, over my shoulder.

A. Okay. This is an example of the NIR stent and, as you can see, it is made of a series of repeating cells,

each of which looks like this (indicating), this laughing guy here.

Each cell here is made of horizontal loops that we call C, C's, and vertical loops, which we call U's.

You heard those names. This is where they belong.

Go on, please.

As the stent is expanded -- stop here -- is expanded by the balloon, the cell opens to a larger diameter. The C part of it becomes shorter in the longitudinal direction, but as you can see, the vertical loops open to compensate for it, such that the stent as a whole does not become shorter. Each cell becomes wider without becoming shorter.

Go on.

And, hence, the total length of the expanded stent remains the same or closely to remaining the same as it was before expansion.

Q. Okay. Now, you testified that you learned from your discussions with the physicians in the 1993/1994 time period that flexibility was an important attribute?

A. Well, I would say that the important attributes that were held important by the physicians I spoke to were flexibility before the stent is expanded, as it is

on the balloon, because this is how it's going to traverse to track through the tortuous, curvy vessels, with as little friction with the vessel wall as friction as you can achieve.

Then, once it is expanded in position, you first under X-ray position the unexpanded stent in a position relative to the lesion you are trying to open, and you want that to understand opened, it will cover as much as possible, the same area that you positioned it in. You don't want the stent to be too long because the direction of the stent with the vessel has some level of injury. So you don't want to injure an area that is not -- you don't want it to be too short so that some of the lesion will not be supported and will continue to protrude in.

So the second thing is the accuracy of judging from the size and position of the stent before expansion where it would end up being after expansion.

The next one is that it will be strong enough and continuous enough, rigid enough, such that the vessel wall with the lesion that tends to recoil, to reclose, will not -- the stent will be strong enough not to close and the scaffolding should be close enough such that tissue will not penetrate between struts.

So if I'm summarizing all of those together,

it's flexibility, no foreshortening, radial force, strong enough, and scaffolding, no protrusion of tissue between struts.

Q. All right. Let's focus on the flexibility of the unexpanded NIR stent.

A. Yes.

Q. And we have I think a series of images that I'd like you to discuss and explain, if you would.

MR. HANLEY: The next one, please.

THE WITNESS: Okay. Go on.

This is the stent. As a matter of fact, when it is crimped, it is even slightly smaller, but this is the size of the cell that we saw and, of course, if instead of a specialized shape, that cell would have, or that opening would have been just a straight slot as to one we found in Palmaz/Schatz, you would not be able to bend it. Two straight lines connected end to end cannot bend.

This one, let's see what happens generally when it bends. You want to bend it downward, what will happen is that this vertical loop (indicating) can become wider and that one narrower and the total shape of the cell is now bent downward.

And vice-versa when you do it upwards.

Can I get it? Yes.

Here, the bottom one becomes wider and the top one becomes narrower, so each and every cell in the structure is flexible. Hence, we call it a flexible closed cell geometry.

And with all cells doing the same thing along the stent and around the stent, the whole stent flexes uniformly, not one point like an articulation point, but everywhere along the length of the stent it can bend by each cell bending this way.

Q. Would you turn in your book to DX-15368?

A. Three six eight?

Q. 15368. Right.

A. Yes. I'm there.

Q. Would you identify that, please?

A. This is a scanning electro microscopy image, cell image, in short, that was taken of a NIR stent, mounted on a balloon, and bent, as it would, when it goes through a curved section of a vessel.

MR. HANLEY: Your Honor, we offer Defendants' Exhibit 15368.

MR. CAVANAUGH: No objection.

THE COURT: Thank you.

DEPUTY CLERK: So marked.

*** (Defendants' Exhibit No. 15368 was received into evidence.)

MR. HANLEY: Would you put that up, please?

BY MR. HANLEY:

Q. All right. And, Doctor, can you explain what the jurors are seeing here?

A. Yes. What we're seeing is a long stent. I believe the one that was taken here was like 30 milliliter long.

This dimension here (indicating) is about 1 millimeter. And as you can see, if that is what the vessel would look like, the stent would take that and would gracefully shape itself because it can bend anywhere. Here or here or there (indicating).

So this is what we -- what we mean when we say uniformly flexible, that it can flex equally along its length.

Q. This stent that's depicted here, is this a relatively long stent?

A. Yes. As I said, I believe it's a 30-millimeter-long stent. It's a very long stent. And before or in a Palmaz/Schatz-like configuration, no such long stents were available because you couldn't use them. You could not push into the vessel very long stents if they are not flexible enough.

Q. Now, you also talked about the scaffolding properties of the NIR stent.

A. Correct.

Q. We have some images directed to that issue.

MR. HANLEY: If we could show those and perhaps you can explain those as well.

BY MR. HANLEY:

Q. All right. What are we seeing here, Dr. Richter?

A. Okay. I mentioned before, if you remember, that, for example, for an articulated stent, such as the Palmaz/Schatz, the gap would be especially large if it were on a curve and the gap would now open on the outside of the curve.

It is important that the scaffolding, the density of scaffolding, would be the same inside a curve or outside a curve.

The special geometry of the flexible cell of the NIR is such that what we are looking at is a cell on the -- can I hold in my hand a model and show where we're looking at?

Q. Sure. If you can find it in the box.

A. I can find it.

Q. I will happy to have somebody help you if you can't.

(Pause.)

THE WITNESS: This is a ten times larger model of the NIR, so we're now looking at the cell on the outside of the curve.

That cell, as you can see, the one that is

painted orange, became longer in order to allow the longer line on the outside, but as it became longer, it -- it was pulled narrower.

Now I think the next image is of a cell on the inside of a curve. Now we're looking at the cell here, on the inside of the curve.

It became shorter by the loops, the U loops, being pushed close, but at the same time, it became wider, so that the difference in area of coverage of the cells inside and the cells outside is minimized by the fact that when the cell becomes long, it becomes narrow, and when it becomes short, it becomes wider.

So that we end up having enough coverage, both on the inside and on the outside of a curved section if this is where the stent is implanted.

MR. HANLEY: Let's see the next slide.

THE WITNESS: Here we see, again, the orange for what would be on the outside and blue for what would be on the inside. But when the stent is straight, there are cells of equal shape and size.

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A. (Continuing) And when the stent is bent, you see what I just explained, the one in orange becomes longer and narrower. The one on the inside becomes shorter but wider.

So the total area is close to unity, but it's not exactly unity.

- - -

A. (Continuing) If it's less than 1.5 to 1, I call it a good ratio. If, on the outside, it would open ten times more than on the inside, then maybe you have too large a gap on the outside.

Q. So let's go on how the NIR stent is made. Can you give the jurors some general overview of that process?

A. Are we talking about the manufacturing process?

Q. Yes, the manufacturing process.

A. Do you want me to do it with the video I've prepared?

Q. Okay. If you want to do it with the video, that will skip a step. Why don't we go right to that.

A. I think we'll stop it at the right places. It would be easier to do.

Stop it here, please.

First of all, we start with a flat panel of metal and the way we form the image in that is very similar to how images of conductable printed circuit boards or chips in the micro electronics industry are formed. We can guess that there is -- I came from that industry before, had something to do with me choosing that way.

EXHIBIT D

REDACTED